

AF



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,379	01/23/2004	Albert Zorko Abram	021706-000420US	7565
20350	7590	10/21/2005	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			HAGHIGHATIAN, MINA	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/763,379

Applicant(s)

ABRAM ET AL.

Examiner

Mina Haghighatian

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 10-12, 14-33, 35-37, 65 and 66 is/are pending in the application.
- 4a) Of the above claim(s) 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 14-33, 35-37, 65 and 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the Declaration, Amendments and Remarks filed on 08/15/05. Claims 1, 35 and 36 are amended, claims 6-8, 38-62 and 64 are cancelled and new claims 65-66 are added. Accordingly, claims 1-5, 10-12, 14-33, 35-37 and 65-66 are pending, of which claims 10-12 are withdrawn.

NOTE: Claims 10-12 depend on a cancelled claim, namely claim 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1616

Claims 1-5, 14-33, 35-37 and 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al (20030118511 A1) in view of Klein et al (5,446,028).

Jones et al teach corticosteroid- containing pharmaceutical compositions comprising a corticosteroid, a quick-break foaming agent, a propellant and a buffering agent. The said composition is applied to the skin site as a foam, which is a thermophobic quick-break foam (see [0006] and [0007]). The quick-break foaming agent comprises an aliphatic alcohol, in an amount of from 40-90%, water in an amount of from 10-40%, at least one fatty alcohol in an amount of from 0.5 to 10% and a surface active agent in an amount of from 0.1 to 15% w/w (see [0008]).

Jones also discloses that the aliphatic alcohol may be selected from ethanol, methanol, isopropanol, etc, or mixtures thereof (see [0014]). The fatty alcohol may be selected from cetyl alcohol, stearyl alcohol, or mixtures of the two, known as octadecan-1-ol (see [0013]). The surface active agent may be selected from ethoxylated sorbitan stearate, palmitate, oleate or mixtures thereof. Suitable surfactant is polysorbate 60 ([0015]). The propellant may be selected from butane, propane, ethane, etc, which is present in an amount of 3-30 or preferably from 3-5% w/w (see [0016]). The composition may contain a buffering agent and the desirable pH level is from 3.0 to 6.0, and most preferably from 4.0 to 5.0 ([0021]). The composition may also comprise a humectant such as propylene glycol, glycerine, sorbitol, etc, present in an amount of from 0.5 to 3.0% w/w (see [0017]).

Jones et al teach that corticosteroids, or a mixture of corticosteroids, are present in the formulation from about 0.01 to 1.0% w/w (see [0018]-[0020] and claim 8). It is also disclosed that in use, the composition is sprayed, producing a semi-solid (i.e. foam or mousse) that is suitable for the topical application to skin or scalp. On application, heat from the skin causes the foam to break down to liquid form (see [0025]). Jones exemplifies a formulation in a table disclosed under section [0028], which discloses amounts of each ingredient. For example the formulation comprises 57.79% ethanol and 33.69% water. Thus the ratio of ethanol : water is 1.7:1, the same as the requirements of instant claim 15.

Jones discloses corticosteroid as the active agent, but does not disclose other active agents suitable for inclusion in the said foam formulation.

Klein et al teaches compositions and method for the treatment of acne including a peroxide and an antibiotic selected from the lincomycin family of antibiotics (see abstract). Exemplary antibiotics include lincomycin and clindamycin and their acceptable salts such as hydrochlorides and phosphates (col. 2, lines 33-38).

Examples 1-6 and 12-13 show various dosage forms comprising clindamycin and benzoyl peroxide, with examples 5 and 12-13 disclosing clindamycin phosphate. Example 12 discloses an aerosol spray comprising from 0.1 to 5% clindamycin phosphate and from 1 to 20% benzoyl peroxide. The suitable pH range for the said topical formulations is from 4.6 to 5.7 (see col. 8, lines 7-17 and claims 3 and 8).

Art Unit: 1616

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the quick-breaking foaming formulations of Jones et al comprising an active agent with the acne treating formulations of Klein et al comprising clindamycin phosphate and benzoyl peroxide with a reasonable expectations of successfully preparing an efficient and stable foam for treating skin disorders such as acne.

Response to Arguments

Applicant's arguments with respect to claims 1-5, 14-33 and 35-37 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's Declaration, indicating conception and reduction to practice of the claimed invention before September 3, 2002 priority date removes Popp publication as prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian
October 13, 2005



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER